DEC - 4 2009

K092603

510(k) Summary

Introduction

According to the requirements of 21 CFR 807.92, the following information provides sufficient detail to understand the basis for a determination of substantial equivalence.

Submitter name, address, contact

Roche Diagnostics
9115 Hague Road
Indianapolis, IN 46250
(317) 521 - 3831

Contact Person: Kathie J. Goodwin

Date Prepared: August 24th, 2009

Device Name

Proprietary names: COBAS INTEGRA Glucose HK Gen. 3 Assay

Common names: Glucose HK Gen. 3

Classification names: Glucose Test System

Regulation Number: 21 CFR 862.1345

Product codes: CFR

Device Description

The cassette COBAS INTEGRA Glucose HK Gen. 3 contains an in vitro diagnostic reagent system intended for use on COBAS INTEGRA SYSTEMS for the quantitative determination of glucose in serum, plasma, urine, and cerebrospinal fluid (CSF).

The test principle is an enzymatic reference method with hexokinase.

Intended use

In vitro test for the quantitative determination of glucose in serum, plasma, urine and cerebrospinal fluid (CSF).

Indications for Use

Glucose measurements are used in the diagnosis and treatment of carbohydrate metabolism disorders including diabetes mellitus, neonatal hypoglycemia, idiopathic hypoglycemia and pancreatic islet cell tumors.

Substantial equivalence

The table below indicates the similarities between the modified COBAS INTEGRA Glucose HK Gen. 3 test and its predicate device COBAS INTEGRA Glucose HK Gen. 3, K061048.

Substantial equivalence – comparison

Feature	COBAS INTEGRA Glucose Gen. 3 Assay Serum/Plasma Application	Predicate Device: COBAS INTEGRA Glucose Gen. 3 Assay Serum/Plasma Application (K061048)
Intended Use	In vitro test for the quantitative determination of glucose in serum, plasma, urine, and cerebrospinal fluid (CSF) on COBAS INTEGRA systems.	Same
Assay Protocol	Enzymatic reference method with Hexokinase	Same
Sample Type	Serum Plasma: Li-heparin, K2-EDTA, K3-EDTA and fluoride plasma	Same
Calibrator	Calibrator f.a.s.	Same
Calibration Frequency	Each lot and as required following quality control procedures	Same
Controls	Precinorm U or Precinorm U Plus And Precipath U or Precipath U Plus	Same
Reagent Stability	Shelf life at 2 to 8°C Integra 400/400 Plus: On-board in use at 10-15°C for 8 weeks Integra 800: On-board in use at 8°C for 8 weeks	Same
Measuring Range	Regular Applications: 4.32 – 720 mg/dL Stat Applications: 4.32 - 541 mg/dL	Regular Applications: 2.16 - 720 mg/dL

Substantial equivalence – comparison

<table>
<tr><th>Feature</th><th>COBAS INTEGRA Glucose Gen. 3 Assay
Serum/Plasma Application</th><th>Predicate Device: COBAS INTEGRA Glucose Gen. 3 Assay
Serum/Plasma Application
(K061048)</th></tr>
<tr><td>Precision – Serum/Plasma</td><td>
Serum – Regular Application:
Repeatability (Within-Run Precision)
<table>
<tr><th>Sample</th><th>Mean (mg/dL)</th><th>CV (%)</th></tr>
<tr><td>HS1</td><td>64.3</td><td>0.69</td></tr>
<tr><td>HS2</td><td>120</td><td>0.78</td></tr>
<tr><td>HS3</td><td>665</td><td>0.70</td></tr>
<tr><td>PNU</td><td>90.8</td><td>0.58</td></tr>
<tr><td>PPU</td><td>247</td><td>0.59</td></tr>
</table>
Intermediate (Between Run Precision)
<table>
<tr><th>Sample</th><th>Mean (mg/dL)</th><th>CV (%)</th></tr>
<tr><td>HS1</td><td>64.3</td><td>1.26</td></tr>
<tr><td>HS2</td><td>120</td><td>1.41</td></tr>
<tr><td>HS3</td><td>665</td><td>1.32</td></tr>
<tr><td>PNU</td><td>90.8</td><td>1.24</td></tr>
<tr><td>PPU</td><td>247</td><td>1.21</td></tr>
</table>
Serum – Stat Application:
Repeatability (Within-Run Precision)
<table>
<tr><th>Sample</th><th>Mean (mg/dL)</th><th>CV (%)</th></tr>
<tr><td>HS1</td><td>64.7</td><td>0.61</td></tr>
<tr><td>HS2</td><td>121</td><td>0.69</td></tr>
<tr><td>HS3</td><td>487</td><td>0.74</td></tr>
<tr><td>PNU</td><td>91.4</td><td>0.58</td></tr>
<tr><td>PPU</td><td>249</td><td>0.57</td></tr>
</table>
Intermediate (Between Run Precision)
<table>
<tr><th>Sample</th><th>Mean (mg/dL)</th><th>CV (%)</th></tr>
<tr><td>HS1</td><td>64.7</td><td>1.08</td></tr>
<tr><td>HS2</td><td>121</td><td>1.40</td></tr>
<tr><td>HS3</td><td>487</td><td>1.10</td></tr>
<tr><td>PNU</td><td>91.4</td><td>1.15</td></tr>
<tr><td>PPU</td><td>249</td><td>1.07</td></tr>
</table>
</td><td>
Serum:
Within-Run Precision
<table>
<tr><th>Sample</th><th>Mean (mg/dL)</th><th>CV (%)</th></tr>
<tr><td>Level I</td><td>80.7</td><td>0.41</td></tr>
<tr><td>Level II</td><td>225</td><td>0.47</td></tr>
</table>
Between Run
<table>
<tr><th>Sample</th><th>Mean (mg/dL)</th><th>CV (%)</th></tr>
<tr><td>Level I</td><td>80.0</td><td>1.09</td></tr>
<tr><td>Level II</td><td>225</td><td>0.90</td></tr>
</table>
</td></tr>
</table>

Substantial equivalence – comparison

<table>
<tr><th>Feature</th><th>COBAS INTEGRA Glucose Gen. 3 Assay
Serum/Plasma Application</th><th>Predicate Device: COBAS INTEGRA Glucose Gen. 3 Assay Serum/Plasma Application (K061048)</th></tr>
<tr><td>Precision – Urine</td><td>
Urine – Regular Application:
Repeatability (Within-Run Precision)
<table>
<tr><th>Sample</th><th>Mean (mg/dL)</th><th>CV (%)</th></tr>
<tr><td>HS1</td><td>8.65</td><td>2.28</td></tr>
<tr><td>HS2</td><td>17.3</td><td>1.05</td></tr>
<tr><td>HS3</td><td>672</td><td>0.53</td></tr>
<tr><td>PNU</td><td>90.8</td><td>0.58</td></tr>
<tr><td>PPU</td><td>247</td><td>0.59</td></tr>
</table>
Intermediate (Between Run Precision)
<table>
<tr><th>Sample</th><th>Mean (mg/dL)</th><th>CV (%)</th></tr>
<tr><td>HS1</td><td>8.65</td><td>2.83</td></tr>
<tr><td>HS2</td><td>17.3</td><td>1.37</td></tr>
<tr><td>HS3</td><td>672</td><td>1.01</td></tr>
<tr><td>PNU</td><td>90.8</td><td>1.24</td></tr>
<tr><td>PPU</td><td>247</td><td>1.21</td></tr>
</table>
Serum – Stat Application:
Repeatability (Within-Run Precision)
<table>
<tr><th>Sample</th><th>Mean (mg/dL)</th><th>CV (%)</th></tr>
<tr><td>HS1</td><td>8.58</td><td>2.71</td></tr>
<tr><td>HS2</td><td>17.4</td><td>1.16</td></tr>
<tr><td>HS3</td><td>476</td><td>0.64</td></tr>
<tr><td>PNU</td><td>91.4</td><td>0.58</td></tr>
<tr><td>PPU</td><td>249</td><td>0.57</td></tr>
</table>
Intermediate (Between Run Precision)
<table>
<tr><th>Sample</th><th>Mean (mg/dL)</th><th>CV (%)</th></tr>
<tr><td>HS1</td><td>8.58</td><td>3.20</td></tr>
<tr><td>HS2</td><td>17.4</td><td>1.65</td></tr>
<tr><td>HS3</td><td>476</td><td>1.09</td></tr>
<tr><td>PNU</td><td>91.4</td><td>1.15</td></tr>
<tr><td>PPU</td><td>249</td><td>1.07</td></tr>
</table>
</td><td>
Urine:
Within-Run Precision
<table>
<tr><th>Sample</th><th>Mean (mg/dL)</th><th>CV (%)</th></tr>
<tr><td>Level I</td><td>15.0</td><td>1.35</td></tr>
<tr><td>Level II</td><td>43.6</td><td>0.64</td></tr>
</table>
Between Run
<table>
<tr><th>Sample</th><th>Mean (mg/dL)</th><th>CV (%)</th></tr>
<tr><td>Level I</td><td>15.1</td><td>0.75</td></tr>
<tr><td>Level II</td><td>43.8</td><td>0.83</td></tr>
</table>
</td></tr>
</table>

Substantial equivalence – comparison

<table>
<tr><th>Feature</th><th>COBAS INTEGRA Glucose Gen. 3 Assay
Serum/Plasma Application</th><th>Predicate Device: COBAS INTEGRA Glucose Gen. 3 Assay Serum/Plasma Application (K061048)</th></tr>
<tr><td>Precision - CSF</td><td>CSF – Regular Application:
Repeatability (Within-Run Precision)
<table>
<tr><th>Sample</th><th>Mean (mg/dL)</th><th>CV (%)</th></tr>
<tr><td>Level I</td><td>57.7</td><td>1.13</td></tr>
<tr><td>Level II</td><td>168</td><td>1.49</td></tr>
</table>
CSF - STAT Application:
Repeatability (Within-Run Precision)
<table>
<tr><th>Sample</th><th>Mean (mg/dL)</th><th>CV (%)</th></tr>
<tr><td>CSF 1</td><td>39.6</td><td>0.63</td></tr>
<tr><td>CSF 2</td><td>283</td><td>0.39</td></tr>
<tr><td>CSF 3</td><td>517</td><td>0.51</td></tr>
<tr><td>PNU Plus</td><td>92.4</td><td>0.53</td></tr>
<tr><td>PPU Plus</td><td>240</td><td>0.43</td></tr>
</table></td><td>CSF – Regular Application:
Within-Run Precision
<table>
<tr><th>Sample</th><th>Mean (mg/dL)</th><th>CV (%)</th></tr>
<tr><td>Level I</td><td>57.7</td><td>1.13</td></tr>
<tr><td>Level II</td><td>168</td><td>1.49</td></tr>
</table></td></tr>
<tr><td>Analytical Sensitivity</td><td>Lower Limits of Measurement:
Limit of Blank = 2.16 mg/dL
Limit of Detection = 4.32 mg/dL</td><td>Lower Detection Limit:
2.16 mg/dL</td></tr>
</table>

Substantial equivalence – comparison

Feature	COBAS INTEGRA Glucose Gen. 3 Assay Serum/Plasma Application	Predicate Device: COBAS INTEGRA Glucose Gen. 3 Assay Serum/Plasma Application (K061048)
Limitations - Interference	Icterus – No significant interference up to an I index of 60 (approximate concentration of conjugated and unconjugated bilirubin: 60 mg/dL or 1026 umol/L)*	Same
	Hemolysis – No significant interference up to an H index of 1200 (approximate hemoglobin concentration: 1200 mg/dL or 744 umol/L)*	Same
	Lipemia – No significant interference up to an L index of 1900. There is a poor correlation between the L index (corresponds to turbidity) and the triglycerides concentration.*	Same
	Other – In very rare cases gammopathy, in particular type IgM (Waldenstrom's macroglobulinemia), may cause unreliable results.	Same
	Drugs – No interference was found at therapeutic concentrations using common drug panels.	Not Specified
	*measured at a glucose concentrations of approximately 63.07 mg/dL and 297.33 mg/dL	

Substantial equivalence – comparison

Feature	COBAS INTEGRA Glucose Gen. 3 Assay Serum/Plasma Application	Predicate Device: COBAS INTEGRA Glucose Gen. 3 Assay Serum/Plasma Application (K061048)
Expected Values	Plasma Fasting: 74 - 109 mg/dL (Per Thomas L. Blutglucose. In: Thomas L, ed. Labor und Diagnose, 6th ed. Frankfurt/Main: TH-Books, 2005:193-199.) Urine 1st morning: 6 - 20 mg/dL 24-h urine: 6 - 17 mg/dL (average of 1350 mL urine/24 h) acc. to Tietz: Serum,Plasma Adults: 74 - 106 mg/dL 60-90 years: 82 - 115 mg/dL >90 years: 75 - 121 mg/dL Children: 60 - 100 mg/dL Neonates (1 day): 40 – 60 mg/dL Neonates (>1 day): 50 – 80 mg/dL Urine 24-h urine: <0.5 g/24 h Random Urine: 1 - 15 mg/dL CSF Children: 60 - 80 mg/dL Adults: 40 - 70 mg/dL	Plasma Fasting: 70 - 115 mg/dL (Per Thomas L, ed. Labor und Diagnose, 4th ed. Marburg: Die medizinische Verlagsgesellschaft 1992.) Same Same Same Same
Method Comparison - Serum	Glucose values for human serum samples obtained on a COBAS INTEGRA 800 analyzer with the COBAS INTEGRA Glucose HK Gen. 3 reagent were compared to those determined on the same analyzer with the same reagent, but with the Stat application. n=79 Passing Bablok y=0.997x + 0.033 mmol/L τ = 0.999 SD (md 95) = 0.067 Linear Regression y=0.997x + 0.032 mmol/L r=1.00 Sy.x = 0.032	

Substantial equivalence – comparison

Feature	COBAS INTEGRA Glucose Gen. 3 Assay Serum/Plasma Application	Predicate Device: COBAS INTEGRA Glucose Gen. 3 Assay Serum/Plasma Application (K061048)
Method Comparison - Urine	Glucose values for human urine samples obtained on a COBAS INTEGRA 800 analyzer with the COBAS INTEGRA Glucose HK Gen. 3 reagent were compared to those determined on the same analyzer with the same reagent, but with the Stat application. n=50 Passing Bablok y=1.00x + 0.002 mmol/L τ = 0.996 SD (md 95) = 0.082 Linear Regression y=1.00x + 0.003 mmol/L r=1.00 Sy.x = 0.041	

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center – WO66-0609
Silver Spring, MD 20993-0002

DEC 4 2009

Roche Diagnostics
c/o Kathie J Goodwin
Regulatory Affairs Consultant
9115 Hague Road, Po Box 50416
Indianapolis, IN 46250

Re: k092603
Trade/Device Name: Cobas Integra Glucose Hk Gen 3 Assay
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose test system.
Regulatory Class: II
Product Code: CFR
Dated: November 3, 2009
Received: November 5, 2009

Dear: Ms. Goodwin:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (301) 796-5760. For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-5680 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Courtney C. Harper, Ph.D.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use Form

510(k) Number (if known): K092603

Device Name: COBAS INTEGRA Glucose HK Gen. 3 Assay

Indications for Use:

In vitro test for the quantitative determination of glucose in serum, plasma, urine and cerebrospinal fluid (CSF).

Glucose measurements are used in the diagnosis and treatment of carbohydrate metabolism disorders including diabetes mellitus, neonatal hypoglycemia, idiopathic hypoglycemia and pancreatic islet cell tumors.

Prescription Use ___x____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K092603